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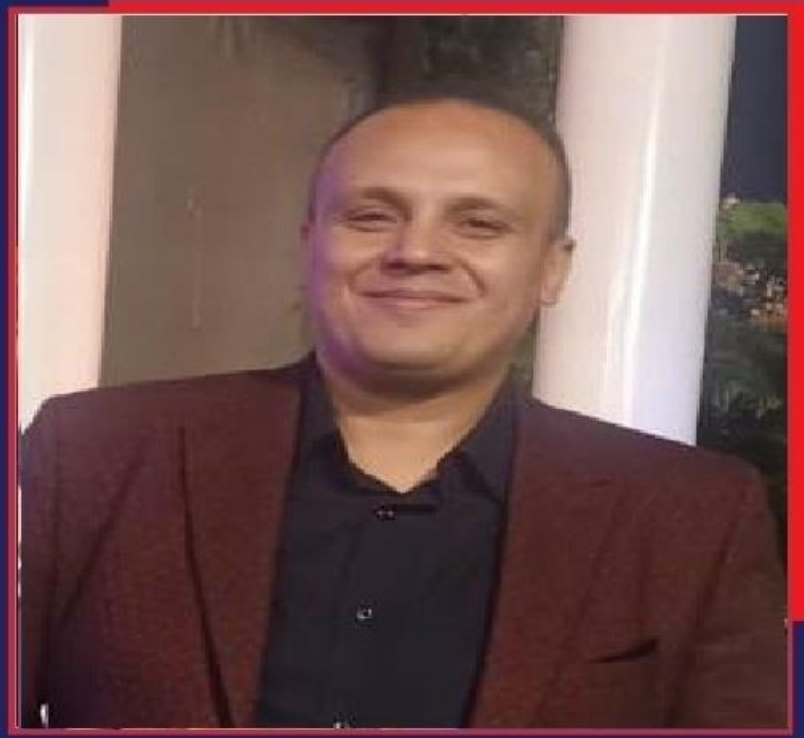
TOLL MANUFACTURING FROM PLANNING TO EXECUTION

Online zoom

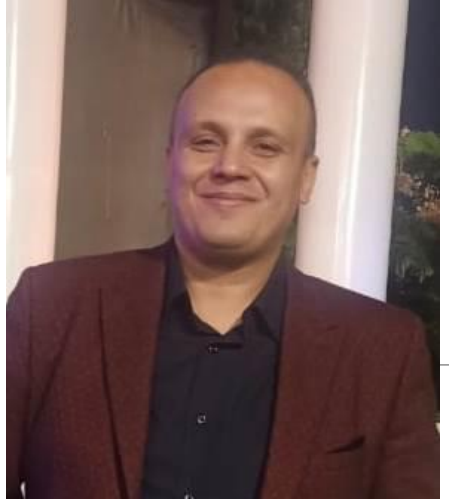
10pm EGY-10 pm KSA-11 pm UAE



Dr. Ahmed Abdel Rahman

Planning & Toll Manufacturing Manager

SAT. 26TH APRIL 2025



Dr. Ahmed Abdel Rahman

Education:

- 01/2025: Doctorate of Business Administration (DBA) from Royal Business College (RBC)
- 06/2022: Master of business administration (MBA) in Supply Chain Management from RBC
- Studied Six Sigma ,TQM, cGMP, Mini MBA, and other technical courses from 2003 till 2019
- 2015: M.Sc. in Science (Excellent) Zagazig University
- 2000: B.Sc. in Science (Very Good) Zagazig University.

Experience:

- Shared for many years as a part time trainer for sterile area courses.
- Toll manufacturing & supply chain Consultant in several organizations e.g. Delta pharm, 6th October University & Ahram Canadian University.
- Total experience 22 years, 14 years in production , Toll manufacturing ,and production planning (all production sectors), and 8 years in planning & Supply chain management till now.

ADWIA, Delta Pharm, Rameda, Biomed, Sovalue, Sedico & Multicare.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TOLL MANUFACTURING FROM PLANNING TO EXECUTION

By: Dr. Ahmed Abdel Rahman

Today we will discuss:

1- Meaning of Toll manufacturing ,

2- Types of Toll Manufacturing.

3- Toll manufacturing steps from planning to Execution

4- Production cycle time with follow up.

5- Planning cycle for your commercial product.

1- Meaning of Toll Manufacturing

- Toll Manufacturing: is an outsourcing arrangement in which you supply the raw materials and pay a fee (or toll) to access the subcontractor's manufacturing capabilities.

- Toll manufacturing or tolling is outsourcing all the production or part of it to a third-party company where you provide all the raw materials or semi-finished products. The work of the third-party company is to process the products or raw materials to the required specification.

TOLL MANUFACTURING TYPES

1- Toll In

It is the process of producing products for another company at your site.

2- Toll Out

It is the process of producing products at another site (plant) for specific products not available at your site.

3- 3rd party contract

Use another party for any activation to delivered for any authorized places.

e.g. Qualification and Validation of plant devices &equipment.

WHEN, WHY& HOW WE USE TOLL MANUFACTURING PURPOSE

When?

Simply you need to produce a product, but you don’t have production area for it.

Also you need to produce a product with specific area (e.g. hormones, sterile dosage form, Lyophilizer, biological products,….etc.)

WHEN & WHY WE USE TOLL MANUFACTURING PURPOSE

Why?

Need to produce essential products have a big demand in market (e.g.

Hormones drugs, Cephalosporin drugs, Beta lactam drugs,….etc.)

How?

We must select site of toll manufacturing upon many criteria:

Quality, response, reputation,….etc.

SELECTION OF TOLL MANUFACTURING SITES

Before select any site to manufactured your products at its site , you should review the following criteria before issue the contract:

1- Reputation

2- Quality

3- Response

4- Agility

5- Prices

ADVANTAGES& DISADVANTAGES OF TOLL MANUFACTURING

Advantages:

- Agility to produce any new product essential and have a big demand at market.

- Increase company portfolio.

- Increase communication cycle with another sites.

ADVANTAGES& DISADVANTAGES OF TOLL MANUFACTURING.

Disadvantages:

- Delay in production due to low response of toll manufacturing site.

- Increase of COGs due to continuous increase in toll fees.

- Decrease cash flow as most of toll plants will need at least 50% of toll fees deposit.

Toll Manufacturing Steps from Planning to Execution

Steps of producing toll product at any site:

1- Choose product identical to our requirements.

a- When we decided to make toll manufacturing for any product , we must choose product identical to our company policy (market demand, company portfolio).

b- We must determine COGs and profit for this product.

c- Market search to know future in this product in market.

d- Contracting steps.

Toll Manufacturing Steps from Planning to Execution

2- Choose product box decree (425, 645, 450,….etc.).

a- Select open box decree that we will choose:

425: producing of one pilot batch (10% of production batch) which will be destructed after finalizing all manufacturing steps and studies (stability, Nodcar, Comparative, Bi-equivalence if needed).

645: producing of 3 production batches which will be ready for market use after finalizing all manufacturing steps and studies (stability, Nodcar, Comparative, Bi-equivalence if needed) with CTD file.

450: New decree like 645 decree with the same steps especially for new drugs just as biological product.

Toll Manufacturing Steps from Planning to Execution

CTD (Common Technical Document) file:

Complete all data of production in an format (R&D, stability, drug master file,….etc.).

So before our production we must check the following:

-API supplier must have drug mater file (DMF) approved from EDA with all approved stability studies (accelerated& long).

-All production development steps must done in authorized place (plant or center).

-We must review all these document to be identical to CTD format.

Toll Manufacturing Steps from Planning to Execution

Determination of Cost of Goods (COGs) and profit margin for the product.

- At beginning, we determine the product's APIs, excipients & packaging materials ,

- We must determine COGs in order to determine the profit margin from this product. This will help us upon choosing sites of high quality with optimum toll fees.

- Also choose many suppliers to overcome Suppliers monopoly.

- Also choose available material from local market to decrease import.

- Deduct or reduce any cost which is not important as much as we can, as specs of packaging materials, better price excipients,….etc.

Toll Manufacturing Steps from Planning to Execution

Market Research to predict product's life cycle in the market.

- Our new product must have a good demand in market with good challenge in market share.

- Add any new ideas for your new product to guarantee good chance in market share such as new packaging designs, new formulation ideas.

So we must choose product out of box not a routine product.

Toll Manufacturing Steps from Planning to Execution

Contacting steps.

The last step, we will start choosing correct site to start issuing manufacturing contract with warehousing annex, and product annex's.

- Review all contract terms (e.g. responsibilities, rent fees, toll fees,…etc.).

Production Cycle Time with Follow-up.

1- After issueing contract, determine our product with all requirements we start the following:

1- Send to toll site all approved documents to be reviewed:

a- R&D documents

b- MOA & test method validation.

c- APIs COAs

d- Review site specs (batch size, production flowchart, packaging materials (1ry & 2ry).

Production Cycle Time with Follow-up.

2- After approval of last step, start to communicate with suppliers for delivering all materials (raw & packaging) or discuss wit toll site to take from them with approved loan.

3- Start pilot or production batch steps

a- Pilot or production batch request

Fast track will be within 3 working days of approval

Normal track within 15 working days of approval

b- Issue batch record , MOA, test method validation, BOM on toll site documents and approved from both sites.

Production Cycle Time with Follow-up.

4- Delivering all materials to toll site with review of EDA inspector at toll plant site all APIs and excipients documents.

5- Review analysis of all materials upon contract policy.

6- Determined date of production with respect to all studies sites you will need such as stability center or toll site labs, bi-equivalence site,….etc.

Production Cycle Time with Follow-up.

7- After production done we will do the following steps:

a- Finalize all production steps till get finished product.

b- Review all analysis steps of finished product.

c- After toll manufacturing site approval, communicate with them and with EDA inspector at their site for withdrawing to your finished product (Nodcar , stability , comparative& bi-equivalence if needed samples).

d- Delivery of all samples to your labs (inside toll manufacturing site or to external centers).

Production Cycle Time with Follow-up.

8- At last, you must review all these steps continuously:

a- Then send Nodcar file to EDA link and after approval of the file, we will delivered samples to Nodcar labs (1st batch to Registration division and 2nd & 3rd batches to Inspection division).

b- Send stability study (Accelerated or long) after approval to EDA link

c- Send Comparative study & Bi-equivalence if needed after approval to EDA link.

9- After you get approval for all these steps , you will get product lisence and you are ready to produce commercial product.

N.B. In 425 decree you will start production of 1st three batches but to Inspection division.

Planning Cycle for your Commercial Production

Planning types:

1- Production planning

This will be toll manufacturing representative which will communicate regular with toll manufacturing site for production plan upon sales forecast with yearly, and monthly plan, and guarantee proper production dates.

2- Demand planning

This who will review availability of all materials before production with sufficient time before production especially for import materials.

- **Local materials: requested at least 1 month before production.**
- **Imported materials: requested at least 3 month before production.**

Planning Cycle for your Commercial Production

3- Material planning

This who will review expiry of your materials to guarantee using all materials before expiry and decrease rent fees at toll site.

Any Question????


Thank you